UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* CHRISTOPHER LESHER, Plaintiffs, v. OPKO HEALTH, INC., BIO-REFERENCE LABORATORIES, AND THE WOMEN'S HEALTH LABORATORY AT GENPATH DIAGNOSTICS, Defendants.	**RELATOR'S COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§3729 *ET SEQ.*** **FILED UNDER SEAL** **DO NOT PLACE ON PACER** CIVIL ACTION NO. _____ **JURY TRIAL DEMANDED**

RELATOR'S COMPLAINT PURSUANT TO
THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729 *ET SEQ.*

1. Relator Christopher Lesher ("Relator"), on behalf of the United States of America, bring this action against Opko Health, Inc., Bio-Reference Laboratories, and The Women's Health Laboratory at GenPath Diagnostics (collectively referred to herein as the "Defendants") for violations of the Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, to recover all damages, civil penalties and all other recoveries provided for under the FCA.

I. THE PARTIES

2. Defendant OPKO Health, Inc. ("OPKO") is a multinational biopharmaceutical and diagnostics company. OPKO's offerings include point-of-care diagnostics, novel molecular diagnostics, and proprietary pharmaceuticals and vaccines. OPKO is incorporated in Delaware with its principal executive offices located at 4400 Biscayne Blvd., Miami, Florida 33137.

3. Defendant Bio-Reference Laboratories ("Bio-Reference"), a New Jersey corporation, is one of the largest full-service clinical diagnostic laboratories in the United States, providing testing and related services to physicians, clinics, and hospitals. Its principal place of business is located at 481 Edward H. Ross Drive, Elmwood Park, NJ 07407. Bio-Reference's

comprehensive testing capabilities and expertise spans molecular diagnostics, anatomical pathology, women's health, oncology and rare disease genetics. On August 20, 2015, OPKO announced the completion of the acquisition of Bio-Reference. From that time to the present, Bio-Reference is a wholly owned subsidiary of OPKO. Currently, Bio-Reference employs more than 5000 people. Bio-Reference Laboratories, and its subsidiaries, has an international presence in more than 50 countries, including laboratory locations in nine states: New York, New Jersey, Maryland, Massachusetts, Rhode Island, Ohio, Florida, Texas and California.

4. The Women's Health Laboratory at GenPath Diagnostics ("GenPath") is a business unit of BioReference Laboratories, Inc. Established in 1986 as a cancer diagnostic unit, GenPath specializes in pathology, cytogenetics, molecular diagnostics, and personalized medicine. GenPath is headquartered at 481 Edward H. Ross Drive, Elmwood Park, NJ 07407.

5. The United States is a plaintiff to this action. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"), the Center for Medicare and Medicaid Services ("CMS"), and other federally funded health care programs including Medicare, Medicaid, Tricare, and the Veterans Administration.

6. Relator Christopher Lesher was hired by Bio-Reference on April 18, 2016 as a Regional Manager overseeing 8 sales representatives in the West Region of Bio-Reference's GenPath Women's Health division. Prior to working with Bio-Reference, Relator had over 13 years of sales experience in the healthcare industry, working at several different companies all over the United States.

7. Relator has standing to bring this action pursuant to 31 U.S.C. §3730(b)(1). Relator brings this action on behalf of the United States for violations of the federal False Claims Act.

8. Relator's complaint is not based on any other prior public disclosures of the allegations or transactions discussed herein in a criminal, civil, or administrative hearing, lawsuit or investigation or in a Government Accounting Office or Auditor General's report, hearing, audit, or investigation, or from the news media. To the extent any alleged public disclosure has occurred, Relator is an original source as that term is defined by 31 U.S.C. §3730(e)(4)(B).

II. SUMMARY OF THE ACTION

9. Defendants are a full service clinical diagnostic laboratory in the United States that provides testing and related services to physician offices, clinics, hospitals, long term care facilities, employers, governmental units and correctional institutions.

10. In violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), Defendants routinely sponsored extravagant dinners, parties and/or events for physicians and physician groups, in exchange for the physician's referral of laboratory business to Defendants. For example, as detailed below, Defendants paid $10,000 for a yacht to host a Christmas party for nineteen (19) medical providers of the Orange Coast Women's Medical Group, in exchange for referrals of business.

11. Defendants also routinely and indiscriminately waived insureds co-payments - knowingly and willfully misrepresenting the actual cost of the procedures and providing financial kickbacks to induce accounts to use Defendants' laboratory testing.

12. More specifically, the payments Defendants receive for providing testing is divided into three elements: 1) the allowable cost that is paid by the insurer (including Medicare Part B), 2) a deductible that is paid by the beneficiary, and 3) a co-pay that is paid for by the beneficiary. For Medicare Part B, the allowable cost and co-payment cost division is 80%-20%, respectively; meaning, if the total cost of the test is $100, Medicare Part B pays $80 of the $100 test and the beneficiary pays the remaining $20.

13. The primary purpose of co-pays is cost control: people are more careful with their own money than they are with someone else's. Requiring beneficiaries to "chip in" helps ensure that beneficiaries will not seek medical testing unless they really need them, thus saving dollars that can be used for other medically necessary testing.

14. Defendants are responsible for billing and collecting the co-pay directly from the beneficiary. From prior to 2012 to the present, in an effort to induce accounts (including physicians, hospitals, practice groups, etc.) to utilize Defendants' testing, Defendants routinely and knowingly waived, and subsequently failed to collect, co-payments owed by Medicare Part B and other government healthcare program beneficiaries.

15. Consequently, physicians and hospitals referred patients to Defendants for testing because it offered the biggest inducement, instead of choosing the testing company that provided the best products/services or best served their needs.

16. By these actions, Defendants have submitted and have caused the submission of false claims to the government, and have made, used, or caused to be made and used false records or statements to get false or fraudulent claims paid by the government plaintiffs.

III. JURISDICTION AND VENUE

17. Jurisdiction is founded under 31 U.S.C. § 3732(a) and (b) and 28 U.S.C. §§ 1331, 1345.

18. Personal jurisdiction and venue are proper in the Southern District of New York pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a), because at least one of the Defendants transacts and has transacted business in the Southern District of New York.

IV. THE MEDICARE PART B PROGRAM

19. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395–1395kkk-1, establishes the Health Insurance for the Aged and Disabled Program, commonly referred to as Medicare.

Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 1395 *et seq*.

20. Medicare is comprised of Parts A (Hospital Insurance), B (Medical Insurance), C (Managed Care Plans), and D (Prescription Drug Program).

21. This case involves claims submitted to Medicare Part B.

22. Medicare Part B is medical insurance that authorizes payment of federal funds for health services, including physician, laboratory, outpatient, diagnostic, and radiology services. *See* 42 U.S.C. § 1395k; 42 C.F.R. § 410.10.

23. Medicare Part B pays for clinical laboratory testing performed by companies such as OPKO, Bio-Reference and GenPath. These independent laboratories perform testing on specimens from patients referred to the independent laboratory by their patients.

24. The Secretary of HHS has overall responsibility for the administration of Medicare. Within HHS, the responsibility for the administration of Medicare has been delegated to CMS.

25. To assist in the administration of Medicare Part B, CMS initially contracted with "carriers" or "fiscal intermediaries." Carriers, typically private insurance companies, were largely responsible for processing and paying Part B claims. 42 C.F.R. §§ 421.1–421.3.

26. Beginning in November 2006, Medicare Administrative Contractors ("MACs") began replacing carriers and fiscal intermediaries. *See* 42 U.S.C. § 1395kk-1; 42 C.F.R. § 421.400 et seq.; 71 F.R. 67960-01, at 68181 (Nov. 24, 2006). MACs generally act on behalf of CMS to process and pay Part A and Part B claims and perform administrative functions on a regional level.

27. Part B providers present claims to Medicare on the CMS Form 1500 Health Insurance Claim Form, where providers certify, *inter alia*, that they complied with all applicable regulations, including the AKS.

28. More specifically, the 1500 Form contains the following notice and certification:

> NOTICE: Any person who knowingly files a statement of claim containing any misrepresentations or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.
>
> NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.

29. Part B providers make additional certifications to the federal government in provider enrollment agreements on CMS Form 855b (Medicare Enrollment Application for clinics/group practices and certain other suppliers) and/or CMS Form 855i (Medicare Enrollment Application for physicians and certain non-physician practitioners), including:

> I agree to abide by the Medicare laws, regulations and program instructions . . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

30. Relying on the veracity of these certifications, CMS makes Medicare payments retrospectively (*i.e.*, after the services are rendered) to Part B providers. For this reason, Medicare payments are often referred to as reimbursements.

V. MEDICARE PART B INDEPENDENT LABORATORY MARKET

31. The majority of laboratory testing services are paid by Medicare Part B on a fee-for service ("FFS") basis. Medicare pays for most outpatient clinical laboratory services based on the Clinical Laboratory Fee Schedule, in accordance with Section 1833(h) of the Social Security Act. The Medicare payment to the laboratory is the lesser of the laboratory's actual charge, the

local fee for a geographic area, or a national limit. Under the Clinical Laboratory Fee Schedule, the amount paid to the laboratory is usually the National Limitation Amount ("NLA"). *See* Medicare Claims Processing Manual [Pub.100-4] Chapter 16- Laboratory Services, Section 20, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf.

32. At the laboratory, tests are done on patient specimens in order to obtain information about the health of a patient as pertaining to the diagnosis, treatment, and prevention of disease.

33. As previously stated, a laboratory that provides testing services submits claims directly to Medicare Part B on a Claim 1500 Form.

34. Defendants have physical laboratories in nine states: New York, New Jersey, Maryland, Massachusetts, Rhode Island, Ohio, Florida, Texas and California.

35. Practically speaking, if a patient is located near one of the Defendants patient service centers, a physician will write a requisition containing his/her NPI number and indicating which diagnostic tests are to be performed ("Requisition"). If that physician does not collect specimens in his/her offices, the patient will go to one of Defendants' patient service centers with the physician's Requisition and have his/her specimen drawn. After the specimen is drawn, it is sent to Defendants' laboratory, the Defendants' laboratory will process the specimen and perform the tests listed on the Requisition. The test results will be sent to the patient's physician and the Defendants' billing department will bill the patient's insurance. In the case of Medicare Part B, the Defendants' billing department will submit a Form 1500 to Medicare Part B and receive reimbursement for the allowable cost, and should submit a bill to the patient for the 20% co-payment amount.

36. In most instances, patients are not located near one of the Defendants' nine physical laboratories. In these instances, when the patient goes to the physician's office, if the physician has a phlebotomist or nurse on staff, the patient's specimens will be collected in the office. The physician will complete a Requisition, and the specimens and Requisition will be packaged in the office and sent to the Defendants' main laboratory in Elmwood, New Jersey. The Defendants laboratory will process the specimen and perform the tests listed on the Requisition. The test results will be sent to the patient's physician and the Defendants' billing department will bill the patient's insurance. In the case of Medicare Part B, the Defendants' billing department will submit a Form 1500 to Medicare Part B and receive reimbursement for the allowable cost, and should submit a bill to the patient for the 20% co-payment amount.

VI. THE TRICARE PROGRAM

37. The federal government reimburses a portion of the cost of laboratory testing services under TRICARE. TRICARE is a medical benefits program established by federal law. 10 U.S.C. § 1071-11 l0b.

38. TRICARE covers eligible beneficiaries, which, inter alia, includes active duty members of the Uniformed Services and their dependents as well as retired members of the Uniformed Services and their dependents. TRICARE is administered by the Defense Health Agency.

39. TRICARE requires a referral and/or prescription from the beneficiary's physician for laboratory tests.

40. Some TRICARE options require participating members to pay a co-pay and/or to meet a deductible. 32 C.F.R. §199.4(f). A provider of services cannot, as a matter of law, waive these co-pay or deductible requirements. 32 C.F.R §199.4(f)(9).

VII. APPLICABLE LAW

A. The False Claims Act

41. The federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, provides, *inter alia*, that any person who (1) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," is liable to the United States for a civil monetary penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(A)-(B).

42. The terms "knowing" and "knowingly" are defined to mean "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

43. The term "claim" means "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Governments behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . . ." 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

44. "[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

B. The Anti-Kickback Statute

45. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration provided to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or harmful to a vulnerable patient population. To protect the integrity of the Medicare and Medicaid programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. See Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

46. The AKS prohibits any person or entity from offering, making, soliciting, or accepting remuneration, in cash or in kind, directly or indirectly, to induce or reward any person for purchasing, ordering, or recommending or arranging for the purchasing or ordering of federally-funded medical goods or services:

> whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both. 42 U.S .C. § 1320a-7b(b). Violation of the statute also can subject the perpetrator to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid.

42 U.S.C.§1320a-7(b)(7) and 42 U.S.C. §1320a-7a(a)(7). Violation of the statute also can subject the perpetrator to exclusion from participation in federal health care programs and, effective

August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. §1320a-7(b)(7) and 42 U.S.C. §1320a-7a(a)(7).

C. Violations of the Anti-Kickback Statute Form the Basis of FCA Liability

47. Congress has long viewed the elimination of kickbacks as central to any efforts to combat Medicare fraud and abuse. *See United States v. Greber*, 760 F.2d 68, 70-71 (3d. Cir. 1985). Because kickback schemes negatively affect the integrity of federal health care programs, the United States has a strong interest in ensuring the continued viability of False Claims Act actions to deter and redress health care fraud predicated upon kickbacks. *United States ex rel. Charles Wilkins and Daryl Willis v. United Health Group, Inc. et al.*, (3d Cir. Oct. 2010)(No. 10-2747) (Brief for the United States as Amicus Curie Supporting Appellant)("Amicus Brief").

48. To protect against the erosion of patient care and patient safety, courts uniformly agree that compliance with the AKS is a material condition of payment under the Medicare program. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *United States ex rel. Conner v. Salina Regional Health Ctr.*, 543 F.3d 1211, 1223 n.8 (10th Cir. 2008); *United States ex rel. McNutt v. Haleyville Medical Supplies*, 423 F.3d 1256, 1259-1260 (11th Cir. 2005); and *United States v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008).

49. These and other courts have held that a person or entity who violates the AKS and submits a claim or causes another to do so has violated the False Claims Act regardless of what form the claim or statement takes. Many of these courts have reasoned that the claims are false, and thus violate the FCA, because there is a false certification – either express or implied – as to compliance with the AKS each time a claim is submitted.

50. Moreover, the AKS was recently amended to expressly state what these courts had already held, namely, that a violation of the AKS constitutes a "false or fraudulent" claim under the FCA. 42 U.S.C. § 1320(a)-7b(g).

V. STATEMENT OF FACTS

51. Defendants perpetuated two different schemes that violated the Anti-Kickback statute: (1) sponsored physician parties, dinners, events in exchange for referrals of business and (2) systematically waived insureds co-payments in exchange for referrals of business. As explained below, these two schemes resulted in referrals of government business.

A. Defendants' Illegal Sponsorships

52. The Anti-Kickback Statute makes it unlawful to pay remuneration in any form to induce the generation of business reimbursable by Medicare, or any other government-funded insurance program. Defendants nonetheless made kickbacks a key part of its strategy to induce the use of its laboratory testing.

53. For example, in November 2016, Miriam Lieberman, a sales representative with Defendants since about 2013, who Relator supervised, requested Relator approve Defendants sponsoring a Christmas party event for a large account in Laguna Beach: the Orange Coast Women's Medical Group. Defendants had been pursuing this group of approximately nineteen (19) medical providers' business for years. The request was for $10,000 which was to be paid to a third party vendor for a private yacht that Orange Coast Women's Medical Group wanted to rent for their annual Christmas party.

54. Relator declined Ms. Lieberman's request stating it would violate the Sunshine Act, Stark Law, and other possible laws set by the Federal Government regulating physicians and the healthcare industry.

55. Subsequently, in Relator's presence, Ms. Lieberman was looking at her phone and reading an email from Relator's supervisor to Ms. Lieberman out loud so that Relator could hear. Ms. Lieberman stated out loud to Relator that her request for the $10,000 for the private yacht had been approved. She further stated that the only condition was the money had to be transferred via check rather than via credit card.

56. Relator confirmed the Defendants sponsored this private yacht later when he was in a meeting with his supervisor, Senior Director of Sales Todd McKinley, and the management members of Orange Coast Women's Medical Group, Naan (Practice Manager) and Wing (Chief Financial Officer). The practice group and Mr. McKinley were talking about how nice the party was and how great it was to have Mr. McKinley and his husband, Lynn, and Ms. Lieberman attend the party.

57. In sum, because Relator wouldn't support paying $10,000 for the private yacht, he was overridden by his supervisor, Mr. McKinley, and then isolated.

58. From his time working at Defendants, Relator learned this was something Defendants did commonly and had even done with Orange Coast Women's Medical Group in years prior. For example, Relator learned his Vice President of Sales, Gary Reeves, and former supervisor, Jack Smith, agreed to sponsor and attended the annual Orange Coast Women's Medical Group Christmas parties in the past. Relator recalls that the 2015 annual Christmas party was located at either the Ritz Carlton or the St. Regis in Laguna Beach. Upon information and belief, those sponsorships grossly exceeded the expense entertainment laws set by the Federal Government for healthcare companies.

59. In addition to sponsoring parties/events, Relator states that Defendants hired two staff members from the account to perform phlebotomy services in the medical center to streamline and simplify work flow at the Orange Coast Women's Medical Center.

60. Sponsorships like the one mentioned above appeared to be encouraged by Bio-Reference's executives. Indeed, one sales representative reported to Relator that at a National Sales Meeting, which included sales representatives from across the country, in Newark, New Jersey in January 2017, Vice President of Sales Gary Reeves and Senior Director of Sales Todd McKinley told sales representatives that if they have a request to sponsor an event for an account, to always ask the supervisors because "you'd be surprised what you could get approved," and then referred to Ms. Lieberman's success with sponsoring the Christmas party.

B. Defendants' Copayment Waiver Scheme

61. As stated above, the second AKS scheme employed by Defendants was the routine and indiscriminate waiver of Medicare Part B copayments.

62. Under Part B, Medicare generally pays 80 percent of the reasonable charges (as established by the Medicare Physician Fee Schedule) for medically necessary services provided to beneficiaries. *See* 42 U.S.C. §§ 1395l(a)(1), 1395y(a)(1)(A). Medicare beneficiaries are generally expected to pay the remaining 20 percent in the form of a copayment, also called a "copay" or "coinsurance" payment. *See* 42 U.S.C. § 1395cc(a)(2)(A)(ii).

63. Waiver of copayments in consideration of a particular patient's financial hardship is permitted in exceptional circumstances. The hardship exception, however, must not be used routinely; it should be used occasionally to address the special financial needs of a particular patient, supported by documentation of financial hardship. Except in such special cases, a good faith effort to collect copayments must be made.

64. As explained below, Defendants routinely waived copayments, without making an individualized determination of financial hardship or exhausting reasonable collection efforts. Additionally, Defendants waived copayments without receiving any supporting documentation or additional information from the patients.

65. By way of background, Bio-Reference is divided into five divisions: BioReference Laboratories (focusing on selling clinical testing to family practice doctors, and specialists), GenPath Oncology (focusing on selling clinical testing to oncologists, urologists, etc.), GenPath Women's Health or "GenPath" (focusing on selling clinical testing to OBGYN, fertility doctors, etc.), Gene DX (focusing on selling clinical testing to geneticists, etc.), and Laboratorio Buena Salud (focusing on selling clinical testing to Spanish speaking patients).

66. Each division had its own Vice President of Sales. All of these Vice Presidents of Sales reported to the Executive Vice President of Sales, Chuck Todd. Chuck Todd reported to Bio-Reference's Chief Executive Officer, Greg Henderson.

67. Executive Vice President Chuck Todd took the lead on communicating to each division; namely the sale strategies and putting pressure on the sales representatives of each division to make sales.

68. All five divisions worked together and collaborated when selling Defendants clinical laboratory tests.

69. The five divisions are organized into approximately 10 geographic regions (it could be less depending on the division) across the United States, with the largest producing region in the Northeast. Each region has a Regional Manager who oversees 8-10 sales representatives selling Defendants' clinical tests in their respective geographic regions. The Regional Managers

report to a Senior Director of Sales, who in turn reports to the Vice President of Sales of the division.

70. Relator worked in the GenPath division and was the Regional Manager of the West Region responsible for 8 sales representatives. Relator initially reported to Senior Director of Sales Jack Smith and later, when Jack Smith changed positions within Bio-Reference and became the Vice President of Revenue Cycle Management, Relator reported to Senior Director of Sales Todd McKinley, along with several other Regional Mangers in his division. The other Regional Managers in Relator's division reported directly to Vice President of Sales Gary Reeves.

71. Every Monday morning at 8:00am PST there was a weekly conference call that lasted about 60 to 90 minutes. Almost all the Regional Managers of the GenPath Women's Health division were expected to be on this weekly call led by the Vice President of Sales Gary Reeves. At the beginning of the call directors and executives of other departments, such as Marketing and IT, were on the call to make announcements and would subsequently log off the call. The rest of the call was devoted to sales-related issues in the division.

72. Relator attended his first weekly Regional Manager's conference call on April 25, 2016. Almost all regional managers of the GenPath Women's Health division were in attendance. The Vice President of Sales for the division, Gary Reeves, was leading the call. During the call, the subject of waiving insureds co-payments was discussed.

73. More specifically, on this call, Gary Reeves was relaying to the Regional Managers that Defendants were changing its billing practices related to co-payments in order to be compliant and avoid exposure from the Anti-Kickback Statute. According to Gary Reeves, his directive and message came from executive leadership, including Chuck Todd.

74. Gary Reeves further informed the Regional Managers, that this change was being effected across all five divisions of the company, and that as part of these "billing changes," the billing department was now required to actually send out bills to insureds containing the amount the insured owed or balances due – *i.e.*, co-payment amounts. Previously, bills with balances (including Medicare Part B copayments due) were being sent to patients once or not at all.

75. Gary Reeves further stated that three bills would be sent out to patients over a period of 90 days. The sales representatives were to inform patients that although the bills were being sent out, if the patient did not pay the bill, the patient would not be sent to collections and after the 90-days, the balance would be written-off and no more bills would be sent.

76. A few of the Regional Managers piped up on the call, expressing their dismay at the change of billing policy and that the Defendants would now be sending bills for balances due to the patients. Relator recalls that Christine O'Rourke, the Regional Manager of the North East (including New York) region in the GenPath division, stated that patients are going to be "irate" when they receive bills. Ms. O'Rourke further stated "do you know how much business we are going to lose?"

77. Ms. Susan Semlack, the Regional Manager of the Las Vegas region in the GenPath division, softly echoed Ms. O'Rourke's comments.

78. In response to the Regional Manager's concerns on the call, Gary Reeves responded that the sales representatives should reiterate to the patients that while they will receive bills, they will only receive three in the first 90 days, and if they don't pay, they will not be sent to collections.

79. The then Senior Director of Sales, Jack Smith, who was also on the call, asked Relator to speak on the importance of being compliant, given Relator's experience with other

companies. At that time, Relator expressed issues with Defendants' practices of waiving insureds co-payments.

80. Relator received no response to his comments.

81. After that first weekly conference call on April 25, 2016, because he made comments regarding being compliant, Relator believes he was blackballed by the other regional sales managers and executives. And he noted tension between himself and the sales representatives he was hired to manage.

82. This was the first time Relator learned Defendants were engaged in this illegal billing practice of waiving copayments. Relator later learned, through a review of documents and conversations with colleagues, that Defendants had been engaged in this practice for years prior to his hiring.

83. After the call, Relator came to understand that the other sales managers were resistant to changing the billing practices because they were afraid of the negative impact it could have on Bio-Reference and GenPath's existing business, meaning they would lose physician clients.

84. Relator also learned that, Bio-Reference/GenPath sales representatives were trained to approach physicians, physician groups and hospitals informing them that if they use/refer to patients' to Bio-Reference's laboratories, then the patient would not have to pay a co-payment. This was attractive to the physicians, physician groups and hospitals because they would not have to receive calls from their patients complaining about a bill and threatening to leave their practices because of the bill.

85. As to how the waivers were handled internally, it was simple: a sales representative would email the Bio-Reference billing department requesting to have the balance due by the patient reduced to zero or written off. The patient was sent a bill once or not at all.

86. In fact, Relator has seen emails dating back to 2013 through the time he left in 2017, from account executives or sales representatives to personnel in the Defendants' billing department asking the billing department to "write-off" any balances due. The sales representatives were instructed when requesting to write-off a balance to write "w/o" rather than, "write-off" so it was less obvious. The billing department always complied with these requests without argument, and the patient would not receive any more bills.

87. After the billing changes were implemented, in or around April 2016, and the billing department was sending bills to patients with balances due, Defendants began to see its revenue/volume drop as it lost clients due to this new policy change.

88. Indeed some of the sales representatives that reported to Relator stated they received angry phone calls from physicians asking why their patients were now receiving bills, and asking the sales representatives not to send the bills. When the sales representatives responded to the physicians, that the billing policy had changed and they were required to send three bills in the first 90 days, but would not send the patient to collections, some of the doctors said that was not good enough and stopped referring business to Defendants.

89. More specifically, sales representative Miranda Lieberman informed Relator that she lost an account, Women's Integrative Health located in Encinitas, California (earning Defendants approximately $200,000 in monthly revenue), stating the doctor informed her that the patients were complaining about the bills and therefore he needed to stop referring business to the Defendants.

90. A seven year, veteran sales representative, stated that she lost clients in Colorado due to the new billing policy.

91. Relator himself dealt firsthand with several accounts located in Washington and Oregon. He, too, received angry phone calls from physicians stating they were going to stop referring business to Defendants because the patients were complaining about receiving bills from Defendants for the clinical testing.

92. Being a supervisor, Relator also spoke with several of his sales representative's accounts explaining the new billing policy, including Tahema Women's Medical Group, Ways Medical Group, and Nickel OB-GYN.

93. Relator recalls explaining the new billing policy to the following groups who eventually stopped referring business as a result of Defendants' sending bills to patients:

a. Galisteo OB-GYN located in Santa Fe, New Mexico stopped referring Defendants business in around June 2016 due to patients complaining about receiving bills;

b. Dr. Vallee located in Santa Fe, New Mexico was a large account (earning Defendants approximately $150,000-$250,000 in monthly revenue) stopped referring business to Defendants in June 2016 because of patient complaints;

c. Los Olivos Women's Medical Group located in the San Francisco Bay Area in California was a large account (earning Defendants approximately $400,000-$500,000 in monthly revenue). Relator's sales representative, Samantha Scantlen, informed Relator that this account stopped referring business to Defendants in early April 2016.

94. Relator also became aware of the loss of specific accounts in the 13-month report he received from the IT department on a monthly basis (which were always sent months late). The

report showed revenue generated from each accounts Relator's sales representatives were overseeing over the previous 13 months. Relator saw a drop in revenue in certain accounts after the Defendants began sending bills to the patients, signifying the accounts or doctors were no longer referring business to the Defendants.

95. The North East region (including New York), for which Ms. O'Rourke was the regional manager of, was one of Bio-Reference's top-producing territories. For the GenPath division alone, Ms. O'Rourke managed several sales representatives, including: Alfred Westamajer, Chris Milin, Sean Leidig, Sean Todd, John Scicutella, John Croce, and Flo Flynn. As a result of the "billing changes" accounts from the North East (New York) GenPath division, and likely other divisions, stopped referring business. By way of example, Mr. Westermajer, who is one of the top-producing representatives in that region, averaging about $10 million in revenue each month, lost over $4 million in revenue from March 2016 (when the changes were implemented) to June 2016. John Croce, also a sales representative in that region, who brought in an average of over $4million each month, lost almost $2 million in revenue from March 2016 (when the changes were implemented) to June 2016.

96. The executive leadership was not happy with this drop in sales and began to pressure sales representatives.

97. Relator attended several in-person meetings where the Executive Vice President of Sales, Chuck Todd, would express his anger regarding the drop in sales and offer suggestions to increase sales.

98. The first of these meetings took place on May 2-3, 2016. This was a Management Meeting that took place in San Jose, California. In attendance was all the Regional Managers from the West Region from each of the five divisions and all sales representatives. The meeting lasted

for about 1.5 days and was intended to provide a location where the Regional Managers could discuss and collaborate on selling Defendants' products in the Western Region. At this meeting, the executives reiterated what was previously announced with regard to the "new billing policy." Namely that three bills would be sent out to patients over a period of 90 days. The sales representatives were to inform patients that although the bills were being sent out, if the patient did not pay the bill, the patient would not be sent to collections and after the 90-days, the balance would be written-off and no more bills would be sent.

99. The second meeting was a National Sales Meeting on May 17-20, 2016. This meeting was located at the Marriott Newark Airport in New Jersey. All the Regional Managers and sales representatives across the GenPath division were in attendance. At this meeting Chuck Todd questioned attendees as to what needed to be done to prevent the loss of business. The attendees would respond that the change in company policy of sending out bills to patients was resulting in the loss of business. In response to these comments, Chuck Todd would tell the attendees to remind the sales representatives that by law, Defendants must send the bills with balance due to the insureds, but that Defendants would not send the insured to debt collections and that any balance due by the patient after ninety (90) days would be reduced to zero after a reasonable attempt to collect has been shown.

100. The third meeting was in February 2017 located in Kiawah Island, South Carolina. At this meeting all Regional Managers across all five divisions were in attendance. For this particular meeting, the Regional Managers of the GenPath division were paired up with the Regional Managers of the BioReference Laboratories division. During this dual meeting, the Executive Vice President of Sales, Chuck Todd, berated the GenPath Women's Health division for its dip in sales, stating that despite the billing changes (*i.e.*, the fact that the company is now

sending bills to patients with balance owed, but not collecting) the BioReference Laboratories division was not experiencing a dip in sales.

101. After Mr. Todd's instruction, Relator noticed that the sales representatives began developing creative practices to achieve patient forgiveness of a balance due. The effectiveness of these creative schemes would be measured by the loss of accounts.

102. One of the creative schemes used by sales representatives to achieve patient forgiveness on an account is the sales representative would communicate to the account (physicians and nurses) to tell their patients that the Defendants would be sending the patient three separate bills, in 30-day increments, and then the bill would go to $0.00. The sales representatives would emphasize that the Defendants would not send the patient to debt collections because the bill would go to $0.00 after 90 days.

103. Relator specifically recalls when one of his sales representatives. Miriam Lieberman tried to implement this scheme in approximately April 2016. Relator received a call from Ms. Lieberman regarding an irate patient, P.V., of Dr. Laurence Fakinos. Ms. Lieberman explained that P.V. was upset because she was told that she would not receive a bill for testing performed at her physician's office and she received a bill for $301.31. Relator called P.V., and P.V. asked "what type of scheme GenPath was running"? P.V. then said she told her doctor she did not want any tests because they were out of her insurance network and that she wasn't sure all of the tests he was ordering was really necessary. P.V. said her doctor and Ms. Lieberman informed her, not to worry and that if she received any bills from Defendants for the testing that she should just "tear them up" and she would not be sent to collections. Relator informed P.V. that she owed $301.31 and that he could place her on a payment plan. Relator also raised this with his then Senior Director of Sales Jack Smith.

104. If the above-mentioned scheme did not work, the next practice engaged in by sales representatives is that the sales representative would ask for approval from their supervisor (manager level or above) to send a request to the Defendants' billing department to have the outstanding balance due to the patient zeroed out, or "written off", and then state one of the following reasons: (a) The account mistakenly sent their lab specimens to Bio-Reference, which should have gone to the in-network lab (this same example would happen in accounts where there was a Bio-Reference paid phlebotomist, which, realistically should not happen). (b) The account did not know the patient's insurance plan was out-of-network with Bio-Reference. (c) The patient was supposed to be cash-pay instead of applying insurance. Again, these are examples of scenarios that would be given to a supervisor and then forwarded to the billing department for approval.

105. Indeed, on December 29, 2016, one of the sales representatives, Shawn Glassman, emailed Bio-Reference's billing department, with a copy to Relator, stating that one of his physician's patients, A.W., received a bill for one of Defendants' tests. Ms. Glassman stated that, the patient stated that had she used Quest, the test would have been 100% covered. The billing department responded stating that the insurance paid $198.02 which left the patient with a balance owed of $247.57. Ms. Glassman requested that this balance be written-off because if the patient had gone to Quest, it would have been covered. Relator responded to Ms. Glassman, copying Todd McKinley, stating that this is the account's responsibility to send to Quest, Ms. Glassman should inform the account to be more careful and that the balance would not be written-off. Todd McKinley responded that he could get Gary Reeves to approve the write-off of the balance to "avoid losing a client." Relator refused to write-off the balance.

106. As discussed above, Relator would consistently not approve sales representatives' requests to have patient's bills "written-off" under any circumstance.

107. Relator's management relationship with the sales representatives was negatively impacted by his refusal to approve to writing-off patient bills and by his expressing disapproval of the billing practices. When sales representatives could not secure his approval to write-off patient balances, they would seek approval from Relator's supervisors. For example, after Ms. Lieberman saw how Relator handled her patient P.V., referenced in ¶103 above, Ms. Lieberman stopped going to Relator for approval and went directly to his supervisor, Todd McKinley.

108. In addition to refusing approval, on multiple occasions Relator spoke up against the creative billing practices discussed above that were promoted by the executive leadership and practiced by the sales representatives.

109. More specifically, Relator spoke up on his first weekly conference call on April 25, 2016, intermittently over the months he was employed by Bio-Reference, and during the sales meeting that occurred in South Carolina in February 2017. He continued speaking up, until he left Bio-Reference on May 19, 2017.

110. Following his outspoken disapproval of the illegal practices as detailed above, the last occurring on February 1, 2017 when Relator attended a manager's meeting at Kiawah Island in South Carolina, Relator was placed on a Performance Improvement Plan ("PIP") by supervisor Todd McKinley when attending a dinner program in Beverly Hills, California on February 23, 2017.

111. When Relator was placed on the PIP, he immediately questioned the validity of the PIP, referencing his leadership success as evidenced by his region's growth and performance.

112. In response, Todd McKinley stated that his region was in disarray due to his lack of adequate field time with Relator's sales representatives and Relator's inconsistency in submitting his weekly travel schedule to Todd McKinley and Gary Reeves.

113. Relator refuted Todd McKinley's accusations, showing a travel schedule with his sales representatives 3-4 days per week, and questioned why he was the only manager being placed on a PIP for these reasons, when other managers would also forget to submit a weekly travel schedule.

114. Relator never received an answer and never received communication from Human Resources regarding the PIP he was given.

115. Relator's performance was re-evaluated in March 2017 and April 2017, however Relator was not removed from the PIP.

116. Finally, after having dealt with harassment long enough, and not wanting to partake in any more illegal billing practices, Relator tendered his resignation on May 19, 2017.

117. Several months after he resigned, he questioned the Defendants' Human Resources personnel regarding the PIP and alleged that it was completely fabricated. The Human Resources department declined to make a comment.

118. Upon information and belief, the harassment endured by Relator was in retaliation for Relator's efforts to stop violations of the False Claims Act.

119. After Relator left the company, Chuck Todd resigned in June/July 2017, Vice President of Sales Gary Reeves was terminated in August or September 2017, and Senior Vice President of Sales Todd McKinley was terminated in October 2017. Upon information and belief, OPKO terminated and/or requested these individuals to leave based on their above-referenced actions.

VI. DEFENDANTS' FALSE CLAIMS

120. As described in detail herein, Defendants routinely and indiscriminately waived Medicare copayments, and failed to satisfy the conditions established by Medicare laws, regulations, and program instructions to support those copayment and deductible waivers.

A. Defendants' False Certifications

121. Defendants executed supplier agreements with Medicare Part B, to which it submitted claims for the reimbursement of laboratory testing it provided to Medicare Part B beneficiaries. In the supplier agreements, Defendants certified:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

122. As detailed above, Defendants submitted claims to Medicare Part B and other government healthcare programs for reimbursement

a. that were tainted by false certifications related to payments to physicians in the form of sponsored events to induce them to utilize Defendants' laboratory tests in violation of the AKS; and

b. of the allowable cost of laboratory testing it provided to beneficiaries, then routinely waived, and/or failed to collect, co-pays from these Medicare Part B and other government healthcare program beneficiaries.

123. Defendants violated the AKS by offering to and/or soliciting from beneficiaries something of value (*i.e.*, the waiver of the copayment and deductible) as an inducement to generate business for themselves payable by government healthcare programs including Medicare Part B. Government healthcare programs, including Medicare Part B, do not cover items that are provided

because of illegal inducements, and all claims for payment for those items are false. In sum, these waivers violate the AKS, and no safe harbor applies.

124. Compliance with the federal AKS is a precondition to payment from Medicare Part B and other federal payors.

125. Each of the claims submitted to Medicare Part B and other government healthcare programs for reimbursement of laboratory testing provided to beneficiaries, was accompanied by an express or implied certification that the transaction was not in violation of federal or state statutes, regulations, or program rules. Each of those certifications was false, because each claim for payment was tainted by the kickbacks detailed in this Complaint.

126. Additionally, the AKS was amended to expressly state that a violation of the AKS constitutes a "false or fraudulent" claim under the FCA. 42 U.S.C. § 1320(a)-7b(g). Thus, each of the claims submitted to Medicare Part B and other government healthcare programs for reimbursement of laboratory testing provided to beneficiaries, was accompanied by an express or implied certification that the transaction was not in violation of federal or state statutes, regulations, or program rules. Each of those certifications was false, because each claim for payment was tainted by the kickbacks detailed in this Complaint. Thus each claim submitted by Defendants was false on its face.

127. Given the specific statements made by Defendants' management and the more than 15 years of regulatory guidance with respect to such arrangements, Defendants –experienced health care providers with detailed knowledge of the laws applicable to government programs – knew that the claims were tainted by the kickback scheme, and thus were not reimbursable by government programs such as Medicare Part B.

128. Knowingly submitting or causing the submission of claims for prescription drugs which are not reimbursable creates liability under the FCA. Thus, each of these claims to the government from Defendants constituted a violation of section 3729 of the FCA.

B. Defendants' False Statements on Its Form 1500s

129. Additionally, Defendants submitted or caused to be submitted CMS Form 1500s for reimbursement for the laboratory tests it provided to Medicare Part B and other government healthcare program beneficiaries. The Form 1500 requests information about the patient, insurance coverage, the diagnoses, and the services provided for which reimbursement is requested. Entry 24F contains a blank title "$ charges" with a space for a separate entry for each supply/procedure. Entry 28 contains a blank titled "Total Charge." The Medicare Carriers Manual and government pronouncements points out that providers are paid based on "actual charges" which is defined as "the amount the physician or supplier actually expects to receive from the patient and/or the third party payer."

130. Thus, Defendants submitted or caused to be submitted a false statement to the government in its CMS Form 1500s when it submitted claims seeking reimbursement based on the full charge, without revealing that the charge contained a waived co-pay element. Specifically, the "charge" entry on the provider's claim forms require that the provider state the total amount, including the co-payment, it expects to collect. For example, when the provider waives the 20% co-pay on a $100 procedure the true charge is not $100, but 80% or $80.

131. Knowingly submitting false claims to the government for reimbursement creates liability under the FCA. Thus, each of these claims to the government from Defendants constituted a violation of section 3729 of the FCA.

COUNT I
Federal False Claims Act
31 U.S.C. §3729(a)(1)(A)

132. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

133. Defendants knowingly submitted and caused the submission of false or fraudulent claims for payment or approval for supplies to officials of the United States Government in violation of 31 U.S.C. §3729(a)(1)(A).

134. By virtue of the false or fraudulent claims that Defendant presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT II
Federal False Claims Act
31 U.S.C. §3729(a)(1)(B)

135. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

136. Defendants knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims to the United States Government in violation of 31 U.S.C. §3729(a)(1)(B).

137. By virtue of the false or fraudulent claims that Defendants made, used or caused to be made or used, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT III
Retaliation
31 U.S.C. §3730(h)

138. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

139. Defendants have a duty under the False Claims Act, 31 U.S.C. § 3730(h), to refrain from taking retaliatory actions against employees who take lawful actions in furtherance of a False Claims Act action, including investigation for, testimony for, or assistance in an False Claims Act action.

140. Relator took lawful actions in furtherance of a False Claims Act action, including but not limited to investigation for, testimony for, or assistance in an action filed under this section and, as such, engaged in protected activity under the False Claims Act and other laws.

141. Despite a lack of prior disciplinary actions, and due to consistent harassment, Relator resigned on May 17, 2017.

142. Relator was discriminated against in the terms and conditions of his employment by Defendants, by and through its officers, agents, and employees because of lawful acts done by him in the furtherance of an action under the False Claims Act.

143. The actions of Defendants damaged and will continue to damage Relator in violation of 31 U.S.C. § 3730(h), in an amount to be determined at trial.

144. Pursuant to 31 U.S.C. § 3730(h), Relator is entitled to litigation costs and reasonable attorneys' fees incurred in the vindication of his reputation and the pursuit of his retaliation claims.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States, demands that judgment be entered in his favor and against Defendants for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes, with respect to the Federal False Claims Act, three times the amount of damages to the Federal Government plus civil penalties of no more than Eleven Thousand Dollars ($11,000.00) and no less than Five Thousand Five Hundred

Dollars ($5,500.00) for each false claim, and any other recoveries or relief provided for under the Federal False Claims Act.

Further, Relator requests that they receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that his award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

WHEREFORE, Relator, on behalf of the United States, demands that judgment be entered in his favor and against Defendants for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes, with respect to the federal False Claims Act, three times the amount of damages to the federal government plus civil penalties of no more than Eleven Thousand Dollars ($11,000.00) and no less than Five Thousand Five Hundred Dollars ($5,500.00) for each false claim, and any other recoveries or relief provided for under the federal False Claims Act.

Further, Relator requests that he be awarded damages as a result of Defendants' violation of 31 U.S.C. § 3730(h), including reinstatement, two times the amount of back pay, interest on the back pay, and compensation for all special damages sustained as a result of the discrimination. Relator further requests that he receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that his award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Dated: February 28, 2018

Respectfully submitted,

BERGER & MONTAGUE, P.C.

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